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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,677	03/11/2004	John Michael Green II	29997/068	6318

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EXAMINER	
CHAO, ELMER M	
ART UNIT	PAPER NUMBER
3737	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/798,677	GREEN ET AL.	
	Examiner	Art Unit	
	ELMER CHAO	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79,81-101,103-108,111-125 and 127-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-79,81-101,103-108,111-125 and 127-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 April 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of the amendment filed 1/18/2008.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/18/2008 has been entered.

Response to Arguments

3. Applicant's arguments filed 1/18/2008 have been fully considered but they are not persuasive.

Regarding Applicants' arguments with respect to Shechtman in view of Bova, Applicants argue that Shechtman teaches away from a single substrate containing both a sensor and a positional device. However, Examiner asserts that Bova provides a teaching for using a system that would determine a global position using an infra-red camera system. Examiner agrees that this modification would obviate fixing the reference sensor 32 from Shechtman to the patient's body, as one of ordinary skill in the art would understand. However, Shechtman's invention would still work if the modification was performed. Modifying Shechtman to contain this feature of global

position as taught by Bova would not take away from the intent of Shechtman's invention, which is to map out the position of an anatomical structure using the tip of the operator's finger (Fig. 4, abstract). Instead, Bova teaches a system and motivation that would only improve on Shechtman's invention by adding accuracy and reducing complexity by tracking the reference using an infrared system, reducing any error that would occur as a result of the reference sensor moving slightly in relation to the fingertip device of item 30. For additional motivation see col. 7, lines 50-61 of US Patent 7,072,707 B2 as incorporated in the accompanied rejection. Knowing this, one of ordinary skill in the art would know to place the reference sensor on the same substrate as the fingertip device so that the operator would not have to deal with two separate devices which are position independent.

Regarding Applicants' arguments with respect to Pearlman, Applicants argue that placing the reference sensor and probe on the same glove would not provide a satisfactory fixed reference point with respect to the patient's spine. Examiner disagrees, however, because of the explanation given above regarding the improvement made to Shechtman's system by modifying it as taught by Bova. Furthermore, using a glove as the substrate would be obvious because the glove is a technique that yields the obvious benefit of making it easier for the operator to use and move (for motivation see Pearlman, Para [0057]).

Regarding Applicants' arguments with respect to Shechtman and the teaching away from a structure adapted to cover an end of a finger of a user or covering a finger tip of the user, Examiner directs Applicants' attention to page 4 of the Office Action

dated 10/18/2007, where Examiner has mentioned that modifying the sensor to be at the tip of the finger would be functionally equivalent to Shechtman's existing invention where the finger-mounted probe of Fig. 4 is set up to detect the position of the tip of the operator's finger. The simplicity of "covering an end of the finger" such that the sensor is at the tip of the finger would be obvious to one of ordinary skill in the art. Furthermore, the fact that Shechtman provides an additional advantage does not necessarily teach against the setup of the instant invention. Rather, it is only a configuration that may provide an additional advantage of allowing an operator to feel the outer surface of a patient's spine, which is not critical to the primary purpose of mapping the contour of the spine. A configuration where the sensor is at the tip of the finger would not take away the ability of the operator to use Shechtman's system to map the contour of the spine.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **Claims 1-3, 5-7, 12-18, 19-21, 23-30, 32, 33, 39, 40-42, 49, 50, 52, 54-56, 58, 59, 65-69, 70, 72, 74-77, 79, 86-93, 95, 96, 98-101, and 108** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. (U.S. 6,524,260 B2) in view of Bova et al. (U.S. 6,390,982) and Galloway, Jr. et al. (U.S. 7,072,707 B2).

Regarding **Claims 1-3, 5-7, 12-16, 18, 19-21, 23-30, 32, 39, 49, 50 and 52,** Shechtman et al. teach a system and method for determining a contour of a spine, comprising a surgical navigation system (Fig. 2, Item 10), mounting a substrate adapted to be removably mounted to an outer surface of a user's body (Fig. 4); a magnetic tracking positional device attached to the substrate (col. 6, lines 59-63; col. 4, lines 3-8); disposing a structure capable of communicating with the positional device (Fig. 4, Item 30), wherein the structure is located adjacent a tip and pad of the user's finger (Figs. 2-4); a first and second circuit for calculating a position of a point on the anatomical structure by correlating a position of the sensor and a position of the structure (Fig. 5; col. 7, lines 1-22; col. 8, lines 25-44); wherein the anatomical spine is mapped by placing the tip of the structure on the point of the anatomical structure to be determined and concatenating the position of a plurality of points (Fig. 6a & 6b).

Shechtman et al. teach the limitations as discussed above but fail to teach a sensor attached to the substrate that can be tracked by the surgical navigation system. However, in a related field of ultrasonic imaging Bova et al. teach using a room as a fixed frame of reference by using an infra-red camera system, thereby permitting global positioning (Fig. 2, Item 28). Furthermore, Shechtman et al. teach that the fingertip device can also contain an ultrasonic transducer to image the vertebrate (Fig. 12a – 12c). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to calculate global positions using the infra-red camera system and a position sensor on the substrate in the configuration of Bova et al.'s invention in order to perform therapeutic and other forms of medical procedures following a diagnosis (for

motivation see Bova et al. (col. 3, lines 15-18; col. 3, lines 38-41)). Furthermore, incorporating the global positioning system would yield in more accurate positioning without worrying about the location of reference sensor (for motivation see col. 7, lines 50-61 of Galloway Jr, et al.). Furthermore, one of ordinary skill in the art would know to place the reference sensor on the same substrate as the fingertip device so that the operator can integrate the reference sensor along with the fingertip device for the ease of use.

Shechtman et al. teach the limitations as discussed above but fail to explicitly teach the structure adapted to cover an end of a finger of the user. However, Shechtman et al. does teach the structure being able to sense the position of the finger tip because the position of the structure itself is placed in a predetermined position with respect to the finger tip (col. 2, lines 23-32). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Shechtman et al. to have the structure designed to be placed at the position of the finger tip, thereby covering the end of the finger as it is functionally equivalent to Shechtman et al.'s current setup. Such a modification would be obvious to try as the main goal is to monitor the position of the tip of the finger and the placement of the structure must be placed in a fixed relationship with the position of the tip of the finger.

Regarding **Claims 17 and 40,** Shechtman et al., Bova et al., and Galloway et al. teach the limitations as discussed above but fail to explicitly teach the positional device switch located in the palm of a hand. However, Shechtman et al. does teach the switch being located adjacent the palm of the hand where it is assessable by the thumb (Fig. 2,

Item 6). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to place the switch in the palm of the hand because such a location would be functionally equivalent as placing the switch slightly above the hand. Placing the switch in the palm of the hand as compared to Shechtman et al.'s location would serve the same purpose of keeping the switch within the reach of one of the fingers of the hand containing the device (for support see the Present Application, Specifications, page 10, top paragraph).

Regarding **Claims 41 and 42,** Shechtman et al., Bova et al., and Galloway et al. teach the limitations as discussed above, but fail to teach the user utilizing a second tool wherein the second tool saves the user time and the position of the point is determined at the same time the second tool is being used. However, Shechtman et al. teach another embodiment wherein a display-type probe (Fig. 14 & 15, Item 70) is used in conjunction with the finger probe (col. 10, lines 5-42). Therefore, it would have been obvious for a person of ordinary skill in the art at the time of the invention to include using a second tool to determine position as described by Shechtman et al. in order to obtain rotation and/or deformation information of the apex vertebra (for motivation see col. 10, lines 29-37).

6. **Claims 6, 13, 14, 30, 33, 54-56, 58, 59, 65-69, 70, 72, 74-77, 79, 86-89, 90-92, 93, 95, 96, 98-101, and 108** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al. and Galloway et al., further in view of Pearlman (U.S. 7,141,019 B2). Shechtman et al., Bova et al., and Galloway et al. teach

the limitations as discussed above but fail to teach the finger-mounted structure being a glove. However, Pearlman teach using a glove attached to sensors (Para [0057]). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Shechtman et al. in view of Bova et al. and Galloway et al. to use a substrate which is a glove in order to create a device that is integrated and easy to use for the operator. Such a modification can be considered applying a known technique to a known device ready for improvement to yield predictable results (for motivation also see Pearlman, Para [0057]).

7. **Claims 8, 9, 11, 34-36, 38, 60-62, 64, 71, 81-83, 85, 103-105, and 107,** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Ustuner (U.S. 6,746,402 B2). Shechtman et al. and Bova et al. teach the limitations as discussed above. They do not teach the tip of the finger-mounted device having a depressible tip. However, in the related field of ultrasonic imaging, Ustuner teaches a finger mountable probe with a depressible tip that will activate the ultrasound device upon sensing of contact (col. 4, lines 44-52, the tip activates upon contact and hence requires pressure to activate). Therefore, it would have been obvious to a person of ordinary skill in the art modify Shechtman et al. in view of Bova et al. to include the contact sensor tip in order to automate the turning on and off of recording the position of the sensor on the device (for motivation see col. 4, lines 44-52).

8. **Claims 4, 10, 31, 37, 57, 63, 78, 84, 97, and 106** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Ustuner, further in view of Sliwa, Jr. et al. (U.S. 6,511,427 B1).

Regarding **Claims 4, 31, 57, 78, and 97**, Shechtman et al, Bova et al., and Ustuner teach the limitations as discussed above but fail to teach tactile feedback to aid the user in maneuvering the structure. However, in the related field of ultrasonic imaging, Sliwa, Jr. et al. teach an ultrasonic probe with pressure-sensing transducers that provide tactile feedback (col. 8, lines 16-39; col. 5, lines 47-64). Therefore, it would have been obvious to a person of ordinary skill in the art to have included pressure sensing transducers with tactile feedback in order to prompt the user to control the force of the device on the skin as the contour of the spine is mapped out (for motivation see col. 8, lines 16-39).

Regarding **Claims 10 and 37, 63, 84, 106**, the addition of the pressure-sensing mechanisms would create a system capable of activating and deactivating the positional device at a predefined pressure.

9. **Claims 22, 53, 73, and 94** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Danisch (U.S. 5,321,257). Shechtman et al. and Bova et al. teach all of the above limitations. They do not teach the use of a fiber optic device to sense position. However, Danisch teaches the use of a single or multiple fiber optic devices to sense position (Fig. 12; col. 6, lines 20-39). Therefore, it would have been obvious to a person of ordinary skill in

the art at the time of the invention to use a fiber optic device to sense position in order to provide a temperature-resistant and dynamic range of measurement (for motivation see col. 9, lines 49-68).

10. **Claims 43, 111-125, 132, 133, 135, and 136** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Ustuner, further in view of Sliwa, Jr. et al., further in view of Danisch, and further in view of Walbrink et al. (U.S. 5,449,356). Shechtman et al., Bova et al., Ustuner, Sliwa, Jr. et al., and Danisch teach all of the above limitations. They do not teach the method of making an incision in a patient's body. However, in the field of minimally invasive surgery, Walbrink et al. teach making an incision to position a surgical tool (abstract). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to incorporate the methods of the minimally invasive probe to the finger-mounted device in order to gain access to the interior origins and tissues of the body (for motivation see col. 1, lines 5-14).

11. **Claims 44-46, and 127-129** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Ustuner, further in view of Sliwa, Jr. et al., further in view of Danisch, further in view of Walbrink et al., and further in view of Magasi (U.S. 4,826,492). Shechtman et al., Bova et al., Ustuner, Sliwa, Jr. et al., Danisch, and Walbrink et al. teach all of the above limitations. They do not teach the method of making an incision with a length between 2.5 cm and

5cm. However, in the field of minimally invasive surgery, it is well-known to one skilled in the art to minimize incisions lengths (col. 1, lines 18-35). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to make an incision length between 2.5 cm and 5 cm in order to be able to insert the probe attached to the user's finger while reducing the amount of discomfort and pain felt by the patient during insertion (for motivation see col. 2, lines 13-18). Furthermore, the specific choice of an incision length of 2.5cm to 5cm is considered a design choice because the Present Application does not specify a particular advantage of such a range (for support see Present Application, Para [0029]).

12. **Claims 47, 48, 51, 130, 131, and 134** are rejected under 35 U.S.C. 103(a) as being unpatentable over Shechtman et al. in view of Bova et al., further in view of Ustuner, further in view of Sliwa, Jr. et al., further in view of Danisch, further in view of Walbrink et al., and further in view of Touzawa et al. (U.S. 2003/0198372A1). Shechtman et al., Bova et al., Ustuner, Sliwa, Jr. et al., Danisch, and Walbrink et al. teach all of the above limitations. They do not explicitly teach the method of making an incision to the knee, hip, or organ of a patient's body. However, in the same field of mapping contours, Touzawa et al. teach a method for determining the contour of an organ (abstract). Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to make incisions at different locations on the body in order to determine the contour of an organ in order to perform quantitative analysis of the organ such as volume measurements (for motivation see Para [0002]).

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art Unit 3737

/E. C./
Examiner, Art Unit 3737
3/17/2008